

REMARKS

Claims 27 and 28 have been amended and are pending in the present application.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. Priority

Applicants have previously, in the amendment of January 11, 2002, inserted in the specification reference to domestic priority as the first sentence of the specification to claim benefit of priority, as noted above.

II. Sequence Compliance

The Office Action requested a computer readable form (CRF) and paper copy of the Sequence Listing with a statement stating that there is no new matter and that the contents of the Sequence Listing and CRF are the same. Applicant submits a paper copy of the Sequence Listing and CRF with a statement that the CRF and the paper copy of the Sequence Listing are the same and there is no new matter.

III. The Rejection of Claims 27-28 under 35 U.S.C. § 112, First Paragraph

Claims 27-28 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Office Action stated:

In the instant case, applicants only disclose that *Fusarium* strains are characterized physically by characteristics such as mycelium extension and cotton-like culture (see page 4, line 27-page 5, line 2). Due to the original misclassification of the host strain of the instant invention as *Fusarium graminearum*, the specific cultural characteristics recited in the specification most closely resemble *Fusarium graminearum* and not *venenatum* (page 5, line 24 through page 6, line 10). Required techniques for the proper execution of identifying *Fusarium venenatum* as well as critical primers and unique cultural details are not provided in the specification. The specification does not disclose the identifying characteristics of a non-toxic, non-toxigenic, non-pathogenic *Fusarium venenatum* NRRL 30747 host cell, which is an essential element of the claims. Neither applicant nor the prior art provide a correlation between the "characteristics" provided in the specification and *Fusarium venenatum* NRRL 30747. Given the diversity of "identifying characteristics", and the inability to determine which will also be adequate to distinguish correct taxonomy of *Fusarium venenatum* NRRL 30747, it is

concluded that the invention must be empirically determined. In an unpredictable art, the disclosure of one species would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

This rejection is respectfully traversed.

The Office Action states: "Due to the original misclassification of the host strain of the instant invention as *Fusarium graminearum*, the specific cultural characteristics recited in the specification most closely resemble *Fusarium graminearum and not venenatum*". Applicants disagree with this statement. The specific cultural characteristics recited in the specification are specific for strain ATCC 20334 (= NRRL 30747). The identifying characteristics associated with strain ATCC 20334 have not changed because the identifying characteristics are inherent to the strain. Only the species name has changed. The specific cultural characteristics recited in the specification, therefore, are identifying characteristics of *Fusarium venenatum* ATCC 20334.

The Office Action also states: "Required techniques for the proper execution of identifying *Fusarium venenatum* as well as critical primers and unique cultural details are not provided in the specification. The specification does not disclose the identifying characteristics of a non-toxic, non-toxigenic, non-pathogenic *Fusarium venenatum* NRRL 30747 host cell, which is an essential element of the claims." Applicants also disagree with this statement. Applicants state on page 6, lines 4-6, of the specification that "the *Fusarium graminearum* is *Fusarium graminearum* Schwabe IMI 145425, deposited with the American Type Culture Collection and assigned the number ATCC 20334 in U.S. Patent No. 4,041,189." The ATCC Catalog references U.S. Patent No. 3,937,654 (issued February 10, 1976) (see attached). U.S. Patent No. 3,937,654 discloses the morphological and growth characteristics of *Fusarium* strain ATCC 20334. The identifying characteristics for strain ATCC 20334, as disclosed in U.S. Patent No. 3,937,654 (see attachment), have not changed simply because the *Fusarium graminearum* strain ATCC 20334 has been reclassified as a *Fusarium venenatum* strain. The identifying characteristics are inherent to strain ATCC 20334 (= strain NRRL 30747). Moreover, Nirenberg, 1995, *Mycopathologia* 129: 131-141 (see attachment), describes the morphological differentiation of *Fusarium sambucinum* Fuckel sensu stricto, *F. torulosum* (Berk. & Curt.) Nirenberg comb. nov. and *F. venenatum* Nirenberg sp. nov. based on growth on PDA and SNA media, methods well known to the art for morphological differentiation at the time of the priority date of the instant application. Applicants submit that the prior art provides the required techniques for identifying other *Fusarium venenatum* strains having the morphological and growth identifying characteristics of strain ATCC 20334.

The Office Action also states: "Neither applicant nor the prior art provide a correlation between the "characteristics" provided in the specification and *Fusarium venenatum* NRRL 30747." Applicants also disagree with this statement. As stated above, U.S. Patent No. 3,937,654 discloses the morphological characteristics of *Fusarium graminearum* ATCC 20334, now *Fusarium venenatum* ATCCC 20334 (= strain NRRL 30747). The identifying characteristics for strain ATCC 20334, as disclosed in U.S. Patent No. 3,937,654, have not changed simply because the *Fusarium graminearum* ATCC 20334 strain has been reclassified as a *Fusarium venenatum* strain. The identifying characteristics of strain ATCC 20334 (= strain NRRL 30747) have been, and probably will continue to be, added to, allowing increasingly subtle differentiation because of the implementation of new molecular techniques, but the original morphological and growth characteristics of the ATCC 20334 strain remain unaltered. This is true whatever new name, *forma specialis* etc. may be applied to the strain - it will always retain its original morphological and growth identifying characteristics.

The Office Action further states: "Given the diversity of "identifying characteristics", and the inability to determine which will also be adequate to distinguish correct taxonomy of *Fusarium venenatum* NRRL 30747, it is concluded that the invention must be empirically determined. In an unpredictable art, the disclosure of one species would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus." Applicants also disagree with these statements. There is no diversity of "identifying characteristics" associated with strain ATCC 20334 (= strain NRRL 30747). The "identifying characteristics" for strain ATCC 20334 are those described in U.S. Patent No. 3,937,654. It is well known in the art that a strain may be reclassified taxonomically as new strains are isolated and differences between the isolates are discovered. Moreover, new methodologies may be developed that enhance the ability to discern differences between strains of presumptively the same genus and species. For example, Yoder and Christenson, 1998, *Fungal Genetics and Biology* 23: 68-80 (see attachment), describe the use of species-specific primers to resolve members of *Fusarium* Section *Fusarium*. O'Donnell et al., 1998, *Fungal Genetics and Biology* 23: 57-67 (see attachment), disclose methodologies for obtaining molecular phylogenetic, morphological, and mycotoxin data for strain ATCC 20334. However, the morphological and growth identifying characteristics for a strain such as ATCC 20334 do not change.

Applicants submit that the specification in combination with the prior does disclose morphological and growth identifying characteristics of a non-toxic, non-toxigenic, non-pathogenic *Fusarium venenatum* NRRL 30747 host cell.

For the foregoing reasons, Applicants submit that this rejection under 35 U.S.C. § 112 has been overcome and respectfully request withdrawal of the rejection.

IV. The Rejection of Claims 27-28 under 35 U.S.C. § 112, Second Paragraph

Claims 27-28 stand rejected under 35 U.S.C. § 112, second paragraph, as being vague and indefinite in that the metes and bounds of "the identifying characteristics" are unclear. It is unclear how to distinguish *Fusarium venenatum* cells having "the identifying characteristics". This rejection is respectfully traversed.

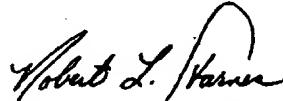
Based on the arguments provided in Section III, the metes and bounds of "the identifying characteristics" are clear.

For the foregoing reason, Applicants submit that this rejection under 35 U.S.C. § 112 has been overcome and respectfully request withdrawal of the rejection.

V. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,



Robert L. Starnes, Ph.D.
Reg. No. 41,324
Novozymes Biotech, Inc.
1445 Drew Avenue
Davis, CA 95616
(530) 757-8100

Date: October 27, 2004